National Government Services

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Comments and Responses Regarding Draft Local Coverage Determination: Biologic Products for Wound Treatment and Surgical Interventions

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As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft LCD Biologic Products for Wound Treatment and Surgical Interventions. The official notice period for the final LCD begins on October 1, 2007, and the final determination will become effective on December 1, 2007.

Multiple comments were received expressing concern about coverage for specific products or product types.

Comment: We are concerned that the Draft LCD, if implemented as is, will effectively remove Dermagraft as a treatment option for physicians and patients who are trying to heal diabetic foot ulcers.
Response: Dermagraft will be covered for FDA approved uses without additional documentation. Non FDA uses will be considered for coverage if requested and supported by acceptable clinical evidence submitted with the request for an article to define expanded coverage.

Comment: I am requesting that Oasis be included in the LCD. (Multiple providers in multiple regions submitted similar requests.)
Response: Multiple comments were received regarding individual products. Individual products are not considered in the policy itself. These comments will be evaluated for coverage as outlined in the LCD.

Comment: Basing coverage decisions on the risk-based FDA device classifications is not appropriate. . . Each device should be evaluated based on its own critically-reviewed, published clinical experience; not only because this can significantly reduce risks and costs, but because it is the right thing to do for patients. (Similar comments were received at a Carrier Advisory Committee Meeting and from another provider.)
Response: The LCD does not base coverage on the FDA classification. It accepts the FDA evaluation of approved Class III products as sufficient for coverage. Since the FDA does not evaluate Class II or Human Tissue products, NGS requires clinical evidence of safety and effectiveness to cover these products.

Comment: Provide coverage only for those products that are approved by FDA to treat, as opposed to manage, chronic cutaneous ulcers and that possess significant clinical evidence of safety and efficacy in wound healing.
Add Skilled Nursing Facility (31) and Nursing Home (32) to the list of "Bill Type Codes."
Response: Coverage articles will determine specific products covered and their indications, frequency of use, etc as well as POS.

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Comment: The reference to Phase II and III studies in the policy is not applicable to these types of products.
Response: We agree that Phase II and Phase III studies do not apply to these products and the references will be deleted from the LCD.

The American Burn Association submitted a lengthy comment related to concerns about the application of this LCD to the treatment of burns.

Comment: Eliminate burns and acute wounds from the scope of this policy by insertion of explicit language to that effect.
Response: This LCD applies to chronic and acute wounds. Burns fall under the category of acute wounds. If a product does not have clinical evidence to support its use in burn wounds, NGS will not cover the product for this use.

Comment: Eliminate autografts and allografts from the policy accordingly.
Response: The LCD does not seek to prevent the use of autograft since this is not included in the list of products covered in this LCD. Burn wounds and the use of allograft products are considered in this LCD. If the particular product is not FDA approved but the literature supports its use in burn patients, NGS will consider publishing a coverage article for that product if requested with the proper documentation.

Comment Delete the provision mandating noncoverage for Human Tissue Products.
Response: As stated in the LCD, Human Tissue Products are not evaluated by the FDA and approved as safe and effective, therefore, NGS will consider coverage of these products when a coverage article is requested and the proper clinical evidence to support the use is submitted. NGS will then publish an article attached to this policy defining the coverage parameters of the product.

One comment was received related to coding instructions.

Comment: Expressed concern regarding the statement in the Coding Guidelines related to the use of modifier -58.
Response: Thank you. We agree, the use modifiers will be defined in individual attached articles as they relate to individual products. The paragraph will be removed from the Carrier Billing Requirements section of the SIA.

One comment was received related to an existing LCD in one of the legacy contractor areas.

Comment: Referring to Apligraft – At the October [2006] meeting, you indicated that we will be able to use four applications but when the policy was printed, it said two.
Response: The existing LCD was modified to allow up to four applications of Apligraft per patient per wound when clinically indicated. Articles attached to the new LCD regarding Apligraft will be effective December 1, 2007 and will reflect this change.